

REMARKS/ARGUMENTS

Claims 1 and 3-53 are currently pending. Applicants have amended claims 1 and 9 to recite "wherein the hindered base is selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethylcyclohexylamine, triethylamine, trisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene". Claims 6-8 and 15-17 have been amended to more specifically claim particular hindered bases. Claims 4, 5, 27, 28, 34, 41, and 44 have been amended to correct dependency and typographical errors in the claims. Claim 2 has been canceled. Claims 48-53 have been added, and are supported by the specification including, for example, paragraph [0060] and the Examples. Applicants submit that there is no new matter in the amendments and respectfully request entry of these amendments.

Applicants note with appreciation that claims 28-41 are currently allowed. Applicants further note that claims 14, 16, and 42-47 are objected to as dependent on a rejected base claim but would be allowable if rewritten to not be dependent on a rejected base claim.

Claims 1-4, 6-7, 9-11, 15, 17, and 19-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,411,984 (Kingston). Kingston discloses reactions of taxol with a basic reagent of pyridine (Figs. 1, 4, 7) or the combination of 1,3-dicyclohexylcarbodiimide and 4-dimethylaminopyridine (DCC/DMAP) (Figs. 2, 3, 5). Kingston does not disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethylcyclohexylamine, triethylamine, trisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 1-4, 6-7, 9-11, 15, 17, and 19-27. Furthermore, Kingston does not disclose or suggest an acid halide reagent as claimed in claims 3-4 and 10-11. Applicants respectfully request withdrawal of this rejection.

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yamaguchi, et al., Bioorganic & Medicinal Chemistry Letters, vol. 9, pages 1639-1644 (Yamaguchi). Yamaguchi

discloses a reaction involving a taxane molecule and DCC/DMAP at Table 1, step iii. Yamaguchi also does not disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethyldicyclohexylamine, triethylamine, triisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 1-2. Applicants respectfully request withdrawal of this rejection.

Claims 1-7, 9-13, 15, 17, and 19-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by de Groot, et al., *Journal of Medicinal Chemistry*, vol. 43, pages 3093-3102 (de Groot). De Groot discloses reacting paclitaxel with 4-nitrophenyl chloroformate and pyridine. As with Kingston and Yamaguchi above, de Groot does not disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethyldicyclohexylamine, triethylamine, triisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 1-7, 9-13, 15, 17, and 19-27. Applicants respectfully request withdrawal of this rejection.

Claims 1-3, 6-7, 9-11, 15, 17, and 24-25 stand rejected under 35 U.S.C. § 102(b) as anticipated by Greenwald et al., *Journal of Organic Chemistry*, vol. 60, pages 331-336 (Greenwald). Greenwald discloses the reaction of 2'-O-acetyltaxol with either pyridine or diisopropylethylamine. As with Kingston, Yamaguchi, and de Groot, Greenwald does not disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethyldicyclohexylamine, triethylamine, triisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 1-3, 6-7, 9-11, 15, 17, and 24-25. Furthermore, Greenwald does not disclose or suggest an acid halide reagent as claimed in claims 3 and 10-11. Applicants respectfully request withdrawal of this rejection.

Claims 1-2 and 6-7 stand rejected under 35 U.S.C. § 102(b) as anticipated by Golik, et al., *Bioorganic & Medicinal Chemistry Letters*, vol. 6, pages 1837-1842 (Golik). As with Kingston, Yamaguchi, de Groot, and Greenwald, Golik does not disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethylcyclohexylamine, triethylamine, triisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 1-3, 6-7, 9-11, 15, 17, and 24-25. Applicants respectfully request withdrawal of this rejection.

Claims 18-23 stand rejected under 35 U.S.C. § 103 as obvious in view of the combination of Kingston and Yamaguchi. As mentioned above, neither Kingston nor Yamaguchi disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethylcyclohexylamine, triethylamine, triisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 18-23. Applicants respectfully request withdrawal of this rejection.

Claims 18-23 stand rejected under 35 U.S.C. § 103 as obvious in view of the combination of Greenwald and Yamaguchi. As mentioned above, neither Greenwald nor Yamaguchi disclose or suggest contacting a solution of a taxane molecule with a hindered base selected from the group consisting of pyridine derivatives substituted at least at the 2-position, N,N-diisopropylisobutylamine, N-ethylcyclohexylamine, triethylamine, triisopropylamine, tripropylamine, imidazole, 1,5-diazabicyclo[4.3.0]non-5-ene, 1,4-diazabicyclo[2.2.2]octane, and 1,8-diazabicyclo[5.4.0]undec-7-ene, as claimed in current claims 18-23. Applicants respectfully request withdrawal of this rejection.

Claim 1 stands rejected under 35 U.S.C. § 112 ¶1 as failing to comply with the written description requirement and as failing to comply with the enablement requirement. Current claim 1 is directed to a method of selectively acylating a starting taxane. Applicants submit that the invention as claimed in current claim 1 is described with sufficient particularity throughout the specification as originally submitted such that one skilled in the art would recognize that the

Applicants had possession of the invention as claimed in current claim 1. Applicants note that page 4 of the specification indicates that the compounds to be acylated may be taxane molecules, and page 11 and Table 1 of the specification provide specific examples of taxane molecules. Furthermore, on pages 26-29, working examples are provided for selective acylation of paclitaxel, cephalomannine, and mixed taxanes.

Applicants further submit that claim 1 is enabled by the disclosure, as the disclosure contains sufficient information to enable one skilled in the art to make and use the invention as claimed in current claim 1 without undue experimentation. "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied." MPEP 2164.01(b). For a claimed genus, representative examples together with a statement applicable to the genus as a whole are ordinarily sufficient for enablement. MPEP 2164.01(c). As noted above, the specification indicates that compounds to be acylated may be taxane molecules and provides specific examples of selective acylation of specific taxane molecules. Therefore, Applicants submit that both the written description and enablement requirements of 35 U.S.C. § 112 are satisfied with respect to claim 1, and respectfully request withdrawal of these rejections.

Claims 4-5, 8, 11, and 27 stand rejected under 35 U.S.C. § 112 ¶2 as failing to particularly point out and distinctly claim the subject matter. Applicants note that claims 4-5 have been amended to depend on claim 3, which includes antecedent basis for the term "acid halide." Claim 8 has been amended to include the term "hindered base" and depend from claim 1, which includes antecedent basis for the term. Claim 11 has been amended to depend on claim 3, which includes antecedent basis for the term "acid halide." Claim 27 has been amended to recite "R_n" rather than "RN." Applicants respectfully request withdrawal of this rejection.

Applicants submitted a Supplemental Information Disclosure Statement on May 11, 2006. Applicants request that the Examiner review the references therein and return the signed Information Disclosure Statement with the next action.

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Applicants respectfully submit that all the claims are in condition for allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor informalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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